AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,028	09/18/2000	Sydney M. Pugh	3477/133(2015	4345

826 7590 11/01/2005

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,028	PUGH ET AL.	
	Examiner	Art Unit	
	Retford Berko	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 53-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement: The Amendment filed 10/14/05 is acknowledged.

Status of Claims

a. Claim 1 is pending in view of applicant's amendment.

b. Claims 2-37 are cancelled in view of the amendment.

c. Claims 38-52 are withdrawn from consideration (Disposition of Claims, Office Action mailed 12/12/02 in Paper No. 10).

d. Claims 53-57 are pending in view of amendment.

e. Though the Amendment filed on 10/14/05 was an After-Final Amendment, Examiner decided to send this final office action to replace the previous final office action, so that examiner would have the opportunity to place on record additional prior art that examiner considers is relevant to the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 remains rejected as unpatentable under 35 U.S.C. 103(a) over Chow et al (US 5, 695, 729) in view of Gerhart et al (US 4, 843, 112) further in view of Sander et al (US 5, 356, 629).

Chow et al (Patent '729) discloses a bone cement composition comprising hydroxyapatite and tetracalcium phosphate (average particle size of less than 15 microns) possessing improved

mechanical strength properties and easy to mold into desired contours; said bone cement is biocompatible and sets at ambient temperature and therefore easy to use (abstract, col 5, lin 5-25 and col 16, lin21-25). Patent '729 also discloses a composition comprising calcium, oxygen and phosphorus that is bioresorbable (col 3, lin 46-48).

Chow (Patent '729) does not disclose ionic radius (i.e. size of particles or size of the constituent elements within the matrix) and does not disclose a drug in the composition.

Gerhart et al (Patent '112) discloses particulate resorbable composition comprising calcium phosphate and hydroxyapatite dispersed in biodegradable polyester (abstract, col 5, lin 20-30 and col 14, lin 25-35). Patent '112 discloses an embodiment of the invention in the form as bone cement comprising autograft or allograft bone particles and that that the composition is implantable and can induce bone growth in surgical applications (col 4, lin 25-30; col 6, lin 50-55 and col 7, lin 6-35). More importantly, Patent '112 discloses an embodiment of the composition that comprises drugs such as antibiotics for sustained drug delivery to sites where the composition is implanted (col 3, lin 55; col 4, lin 5-10 and col11, lin 55-60).

Sander et al (Patent '629) discloses a composition suitable for bone repair comprising biocompatible particles dispersed in a matrix than can be implanted into defective bone tissue (abstract, col 2, lin 35-40, col 3, lin 50-55 and col 5, lin 35-40). Patent '629 discloses the use of drugs and other substances that can induce bone growth in the composition (col 4, lin 55-65; continuing to col 5, lin 1-15). Patent '629 discloses that the biocompatible particles of any size may be used in the composition and that matrix material can be conveniently comminuted to the appropriate particle size of mixing (col 4, lin 30-39 and col 35-40).

One of ordinary skill in the art would be motivated to prepare a composition comprising calcium phosphate and other ingredients (thus using a compound comprising calcium, oxygen and phosphorus), pharmaceutical agents and bone inducing growth factors to form a bone cement composition as disclosed in the prior art cited. By substituting elements having ionic radii that is convenient, thereby control the particle size in the composition forming the bone cement matrix, one of ordinary skill would expect to obtain a composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the antibiotic action of the drugs incorporated into the composition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

Claims 1 and 53-57 are rejected under 35 U.S.C. 103(a) as unpatentable over Chow et al (US 5, 695, 729) in view of the combination of Gerhart et al (US 4, 843, 112), Sander et al (US 5, 356, 629) and Kasuga et al (US 5, 232, 878).

The disclosures of Chow et al (Patent '729), Gerhart et al (Patent '112), Sander et al (Patent '629) have been discussed above (paragraphs 4-7).

None of the Patents disclose the use of boron in forming a biomaterial composition.

Kasuga et al (Patent '878) discloses a process for producing stabilized biocompatible inorganic biomaterials comprising compounds such as calcium phosphate, calcium oxide, phosphorus pentoxide, silicon dioxide, magnesium oxide and aluminium oxide (abstract, col 21, lin 1-10). Patent '878 discloses that the inorganic biomaterial is useful as biomaterial for artificial bones, dental implants etc (abstract). More importantly, Patent '878 discloses that the biomaterial can optionally contain, in addition to the elements or compounds used in the

invention; at least one component selected from a group of compounds including boron oxide (col 5, lin 10-25).

One of ordinary skill in the art would be motivated to prepare an inorganic biomaterial that is biocompatible and make a composition comprising calcium phosphate and other ingredients (thus using a compound comprising calcium, oxygen and phosphorus), pharmaceutical agents and bone inducing growth factors. By optionally adding boron oxide to the composition, one of ordinary skill would expect to obtain a bone repair composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the controlled release of antibiotic drugs incorporated into the composition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 53-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17-23 of U.S. Patent No. 6, 323, 146.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn toward almost identical inventions of biomaterial composition comprising calcium, oxygen and phosphorus and one element substituted with another element having ionic radius of 0.1-0.6. In the case of the instant claims, a pharmaceutically active ingredient is added to the composition. It would have been obvious to one of ordinary skill to add the active ingredient to the composition in order to achieve uptimal treatment targeted to an individual patient's need for a specific purpose (e.g. adding an antibacterial agent to the composition in order to combat bacterial infection.

The following prior art is considered pertinent to applicant's claims and are placed on the record, but are not relied upon in the present rejections: (a) Yasukawa et al (US 5, 780, 281). Yasukawa discloses a method of making implantable, biocompatible fibrous matrix material for use in bone growth (col 1, lin 29, lin 52-55), wherein boron may be substituted or added to the slurry material and wherein the boron functions to lower the melting point of the fiber material, promoting fiber/fiber fusion at fiber intersections and produce uniform particles (col 6, lin 25-41). The cement or paste consistency enables hyddroxyapatite to conform to contours of a bone defect (see Chow, Patent '729, col 5, lin 3032). The reference is not relied upon because though boron is added to the biocompatible matrix material, there is no evidence or suggestion that a chemical substitution occurs in the matrix structure (b) Pugh et al (US 6, 323, 146) disclosed biomaterials wherein boron or silicon substitute other elements in the composition structure (abstract, col 34, lin 50-60). The reference is not used because the publication date or filing date was later than the priority date claimed by applicant.

Response To Arguments

Applicant's arguments have been considered but are not found persuasive:

Applicant argues that the references in the prior art of record do not teach elemental substitution and also fail to provide motivation for the combination of the hydroxyapatite composition with a drug.

In response, Chow et al disclosed a biocompatible cement or pasteas a substitute precursor for skeletal reconstruction and that one may also use any other types of calcium and phosphate containing compounds to prepare the mixture with Ca/P ratio and non-phosphate components in the mixture that undergoes oxidation reactions (col 5, lin 47-54 and col 7, lin 42-59). The reactions do not exclude elemental substitution. Further, Patent '878 disclosed that the biomaterial can optionally contain, in addition to the elements or compounds used in the invention; at least one component selected from a group of compounds including boron oxide (col 5, lin 10-25). By optionally adding boron oxide to the composition and subjecting the bone cement to oxidation, one of ordinary skill would expect to obtain a bone repair composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the controlled release of antibiotic drugs incorporated into the composition.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600